DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4491]

Reuse of Single Use Devices; FDA's Proposed Strategy; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Reuse of Single Use Devices-FDA's Proposed Strategy. The topic to be discussed is the current practice of reprocessing and reusing devices that are labeled, or otherwise intended, for only one use and FDA's proposed strategy to address concerns regarding this practice.

Date and Time: The meeting will be held on December 14, 1999, 8 a.m. to 5:30 p.m.

Location: The meeting will be held at the University of Maryland Auditorium, 9640 Gudelsky Dr., Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Heather Howell, Center for Devices and Radiological Health (HFZ–205), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD, 20850, 301-594-3252, FAX 301–443–7185, Internet site: http://www.fda.gov/cdrh/reuse, e-mail: reuse@cdrh.fda.gov.

Registration and Requests fur Oral Presentations: Please register online on the Internet at http://www.fda.gov/cdrh/reuse by December 1, 1999. There is no charge to attend this meeting, but advance registration is requested due to limited seating. Those desiring to make formal oral presentations should submit a brief statement of the general nature of their presentation, the names and addresses of the proposed participants, and an indication of the approximate time requested to make their presentation. The time allotted for each presentation is limited.

Written comments may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by December 1, 1999.

If you need special accommodations due to a disability, please contact Heather Howell at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the availability of a document entitled "FDA's Proposed Strategy on Reuse of Single-Use Devices' ' in the **Federal Register** of November 3, 1999 (64 FR 59782). The document presents the agency's current thinking about the best way to address the concerns regarding the practice of reprocessing and reusing devices that are labeled, or otherwise intended, for only one use. The agency is interested in discussing this proposed strategy, and it is soliciting comments, proposals for alternative approaches, and information on this issue.

II. Electronic Access

In order to receive "FDA's Proposed Strategy on Reuse of Single Use Devices" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 800-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 2525 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of "FDA's Proposed Strategy on Reuse of Single Use Devices" may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes "FDA's Proposed Strategy on Reuse of Single Use Devices," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications

and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

Dated: 12 Nov '99
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David W. Feigal, Jr.
Director
Center for Devices and Radiological Health

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